

# Bibliography

## 61-1 Chemical Identity

MRID	Citation Reference
45758901	Helmer, D. (2002) Product Identity, Composition and Enforcement Analytical Method of Xamox 3OL: Lab Project Number: PPD-20: AF-1262/1: TDS BS 9813. Unpublished study prepared by Sandoz Agro Ltd. 83 p.
45759001	Helmer, D. (2002) Product Identity, Composition and Enforcement Analytical Method of XAMOX 10TK: Lab Project Number: PPD-19: AF-1262/1. Unpublished study prepared by Janssen Pharmaceutica, N.V. 34 p.

## 61-2 Description of Beginning Materials and Manufacturing Proces

MRID	Citation Reference
45758901	Helmer, D. (2002) Product Identity, Composition and Enforcement Analytical Method of Xamox 3OL: Lab Project Number: PPD-20: AF-1262/1: TDS BS 9813. Unpublished study prepared by Sandoz Agro Ltd. 83 p.
45759001	Helmer, D. (2002) Product Identity, Composition and Enforcement Analytical Method of XAMOX 10TK: Lab Project Number: PPD-19: AF-1262/1. Unpublished study prepared by Janssen Pharmaceutica, N.V. 34 p.

## 61-3 Discussion of Formation of Impurities

MRID	Citation Reference
45758901	Helmer, D. (2002) Product Identity, Composition and Enforcement Analytical Method of Xamox 3OL: Lab Project Number: PPD-20: AF-1262/1: TDS BS 9813. Unpublished study prepared by Sandoz Agro Ltd. 83 p.
45759001	Helmer, D. (2002) Product Identity, Composition and Enforcement Analytical Method of XAMOX 10TK: Lab Project Number: PPD-19: AF-1262/1. Unpublished study prepared by Janssen Pharmaceutica, N.V. 34 p.

## 62-1 Preliminary Analysis

MRID	Citation Reference
45852801	Mollica, J.; Lala, M. (2002) Stability Study of the Manufacturing Product Formulation LAg2001 135 (10% R170051) and of the End-Use Product Formulation LAg2000 493 (2.5% R95137 and 0.5% R170051): Final Report: Lab Project Number: AGR 381: JANSSEN-1391: TDS BS 9813. Unpublished study prepared by Pyxant Labs Inc. 228 p. {OPPTS 830.1700, 830.6317}

62-2 Certification of limits

MRID	Citation Reference
45758901	Helmer, D. (2002) Product Identity, Composition and Enforcement Analytical Method of Xamox 3OL: Lab Project Number: PPD-20: AF-1262/1: TDS BS 9813. Unpublished study prepared by Sandoz Agro Ltd. 83 p.
45759001	Helmer, D. (2002) Product Identity, Composition and Enforcement Analytical Method of XAMOX 10TK: Lab Project Number: PPD-19: AF-1262/1. Unpublished study prepared by Janssen Pharmaceutica, N.V. 34 p.

62-3 Analytical Method

MRID	Citation Reference
45758901	Helmer, D. (2002) Product Identity, Composition and Enforcement Analytical Method of Xamox 3OL: Lab Project Number: PPD-20: AF-1262/1: TDS BS 9813. Unpublished study prepared by Sandoz Agro Ltd. 83 p.
45759001	Helmer, D. (2002) Product Identity, Composition and Enforcement Analytical Method of XAMOX 10TK: Lab Project Number: PPD-19: AF-1262/1. Unpublished study prepared by Janssen Pharmaceutica, N.V. 34 p.
45759002	Cervantes, T.; Lala, M. (2001) A Limited Product Chemistry Analysis of the Manufacturing Product Formulation LAg2001 135 (10% R170051) and of the End-Use Product Formulation LAg2000 493 (2.5% R95137 and 0.5% R170051): Final Report: Lab Project Number: AGR 382: 1385: TDS BS 9813. Unpublished study prepared by Pyxant Labs Inc. 213 p. {OPPTS 830.1700, 830.6302, 830.6303, 830.6304, 830.6315, 830.6319, 830.6320, 830.7000, 830.7100, 830.7300}

63-0 Reports of Multiple phys/chem Characteristics

MRID	Citation Reference
45759002	Cervantes, T.; Lala, M. (2001) A Limited Product Chemistry Analysis of the Manufacturing Product Formulation LAg2001 135 (10% R170051) and of the End-Use Product Formulation LAg2000 493 (2.5% R95137 and 0.5% R170051): Final Report: Lab Project Number: AGR 382: 1385: TDS BS 9813. Unpublished study prepared by Pyxant Labs Inc. 213 p. {OPPTS 830.1700, 830.6302, 830.6303, 830.6304, 830.6315, 830.6319, 830.6320, 830.7000, 830.7100, 830.7300}

63-17 Storage stability

MRID	Citation Reference
45852801	Mollica, J.; Lala, M. (2002) Stability Study of the Manufacturing Product Formulation LAg2001 135 (10% R170051) and of the End-Use Product Formulation LAg2000 493 (2.5% R95137 and 0.5% R170051): Final Report: Lab Project Number: AGR 381: JANSSEN-1391: TDS BS 9813. Unpublished study prepared by Pyxant Labs Inc. 228 p. {OPPTS 830.1700, 830.6317}

81-1 Acute oral toxicity in rats

MRID	Citation Reference
45758902	Moore, G. (2001) Acute Oral Toxicity Study in Rats: LAg2000 493: Lab Project Number: 11125: AGR 394: P320. Unpublished study prepared by Product Safety Labs. 23 p. {OPPTS 870.1100}
45759003	Moore, G. (2001) Acute Oral Toxicity Study in Rats--Defined LD50: LAg2001 135: Lab Project Number: 11131: AGR 394; P320. Unpublished study prepared by Product Safety Labs. 24 p. {OPPTS 870.1100}

81-2 Acute dermal toxicity in rabbits or rats

MRID	Citation Reference
45758903	Moore, G. (2001) Acute Dermal Toxicity Study in Rats--Limit Test: LAg2000 493: Lab Project Number: 11126: AGR 395: P322. Unpublished study prepared by Product Safety Labs. 15 p. {OPPTS 870.1200}
45759004	Moore, G. (2001) Acute Dermal Toxicity Study in Rats--Limit Test: LAg2001 135: Lab Project Number: 11132: AGR 395: P322. Unpublished study prepared by Product Safety Labs. 15 p. {OPPTS 870.1200}

81-3 Acute inhalation toxicity in rats

MRID	Citation Reference
45758904	Moore, G. (2001) Acute Inhalation Toxicity Study in Rats--Limit Test: LAg2000 493: Lab Project Number: 11127: AGR 396: P330. Unpublished study prepared by Product Safety Labs. 22 p. {OPPTS 870.1300}
45759005	Moore, G. (2001) Acute Inhalation Toxicity Study in Rats--Limit Test: LAg2001 135: Lab Project Number: 11133: AGR 396: P330. Unpublished study prepared by Product Safety Labs. 22 p. {OPPTS 870.1300}

81-4 Primary eye irritation in rabbits

MRID	Citation Reference
45758905	Moore, G. (2001) Primary Eye Irritation Study in Rabbits: LAg2000 493: Lab Project Number: 11128: AGR397: P324. Unpublished study prepared by Product Safety Labs. 17 p. {OPPTS 870.2400}
45759006	Moore, G. (2001) Primary Eye Irritation Study in Rabbits: LAg2001 135: Lab Project Number: 11134: AGR 397: P324. Unpublished study prepared by Product Safety Labs. 17 p. {OPPTS 870.2400}

81-5 Primary dermal irritation

MRID	Citation Reference
45758906	Moore, G. (2001) Primary Skin Irritation Study in Rabbits: LAg2000 493: Lab Project Number: 11129:

AGR 398: P326. Unpublished study prepared by Product Safety Labs. 15 p. {OPPTS 870.2500}

45759007 Moore, G. (2001) Primary Skin Irritation Study in Rabbits: LAg2001 135: Lab Project Number: 11135: AGR 398: P326. Unpublished study prepared by Product Safety Labs. 15 p. {OPPTS 870.2500}

81-6      **Dermal sensitization**

MRID	Citation Reference
45758907	Moore, G. (2001) Dermal Sensitization Study in Guinea Pigs (Buehler Method): LAg2000 493: Lab Project Number: 11130: AGR 399: P328. Unpublished study prepared by Product Safety Labs. 24 p. {OPPTS 870.2600}
45759008	Moore, G. (2001) Dermal Sensitization Study in Guinea Pigs (Buehler Method): LAg2001 135: Lab Project Number: 11136: AGR 399: P328. Unpublished study prepared by Product Safety Labs. 24 p. {OPPTS 870.2600}

810.3600      **Structural treatments**

MRID	Citation Reference
46632601	Nicholas, D. (2005) Evaluation of Janssen Formulations in a Field Stake Test: Interim Report: 3-Year Evaluation: R102622, R170051. Project Number: PPD/38, E7/01, E7/03. Unpublished study prepared by Mississippi State University. 129 p.

830.1550      **Product Identity and composition**

MRID	Citation Reference
48166104	Goodwine, W. (2010) Composition of the Custom Blend Lag 2006 013 Containing Xamox 10 TK and Evipol 10 TK. Unpublished study prepared by Janssen PMP. 7 p.

830.1650      **Description of formulation process**

MRID	Citation Reference
46177101	Helmer, D. (2002) Product Identity, Composition and Enforcement Analytical Method of XAMOX 3OL. Project Number: PPD/20. Unpublished study prepared by Janssen Pharmaceutica. 6 p.

830.1700      **Preliminary analysis**

MRID	Citation Reference
46567601	Helmer, D. (2005) Interim Report: Field Termite Test of Commercial Wood Composites Treated with Janssen Experimental Termiticides: (Xamox 3 OL). Project Number: E26639. Unpublished study prepared

by Michigan Technological University. 8 p.

**875.2800      Description of human activity**

MRID	Citation Reference
46494202	Helmer, D. (2005) Xamox Worker Exposure Estimate for Treating End Cuts. Unpublished study prepared by Janssen Pharmaceutica Inc. 4 p.

**875.2900      Data reporting and calculations**

MRID	Citation Reference
46494201	Van den Heuvel, H. (2002) Assay of Xamox in a Surface Wipe Test. Project Number: 02048. Unpublished study prepared by Janssen Pharmaceutica Inc. 9 p.

**Non-Guideline Study**

MRID	Citation Reference
45758900	Janssen Pharmaceutica, Inc. (2002) Submission of Product Chemistry, Toxicity and Efficacy Data in Support of the Application for Registration of Xamox 3 OL. Transmittal of 13 Studies.
45758908	Helmer, D. (2001) Termite Response to Xamox 3OL Treated Wood: Lab Project Number: PPD-21: DK/12/2001: MAT 486/2000. Unpublished study prepared by Janssen Pharmaceutica and Auburn University. 40 p.
45758909	Nicholas, D.; Parikh, S. (2002) Final Report--Testing The Termite Resistance of Janssen Pharmaceutica Formulation--LAG 2000 493: Lab Project Number: AWP A E1-97/LAG 2000: E1-97/LAG 2000 493. Unpublished study prepared by Mississippi Forest Products Laboratory. 22 p. {OPPTS 810.3600}
45758910	Creffield, J.; Owen, R.; Chew, N.; et al. (2002) Laboratory Bioassay to Determine the Termiticidal Efficacy of the Candidate Insecticide R 170051: Lab Report Number 1153. Unpublished study prepared by Ian Wark Laboratories, Clayton, Aust. 15 p. {OPPTS 810.3600}
45758911	Hertel, H. (2001) Determination of the Preventative Action of the Formulation "R 170051" Against Recently Hatched Larvae of the House Longhorn Beetle according to EN 46 (1998): Lab Project Number: 4121 HB A. Unpublished study prepared by BAM. 8 p. {OPPTS 830.1700}
45758912	Hertel, H. (2002) Determination of the Preventative Action of the Formulation "R 170051" Against Recently Hatched Larvae of the House Longhorn Beetle (Hylotrupes bajulus (L.)) after Leaching according to EN 84 (1997): Lab Project Number: 4121 Hb B. Unpublished study prepared by BAM. 8 p. {OPPTS 830.1700}
45758913	Larkin, G. (2002) Interim Report: Field Termite Test of Commercial Wood Composites Treated with Janssen Experimental Termiticides: Lab Project Number: E26639. Unpublished study prepared by School of Forestry and Wood Products. 22 p. {OPPTS 830.1700}
45759000	Janssen Pharmaceutica (2002) Submission of Product Chemistry and Toxicity Data in Support of the Application for Registration of XAMOX 10TK. Transmittal of 8 Studies.
45852800	Janssen Pharmaceutica Inc. (2003) Submission of Product Chemistry Data in Support of the Application for Registration of Xamox 10TK Manufacturing Concentrate Insecticide. Transmittal of 1 Study.

45938900 Janssen Pharmaceutica (2003) Submission of Exposure, Risk, Fate, and Use Data in Support of the Application for Registration of Xamox 3OL. Transmittal of 7 Studies.

45938907 Goodwine, W. (2003) Product Use Information and Description of Human Activity for Pressure and Non-Pressure Wood Treatment Processes: Lab Project Number: PPD-27. Unpublished study prepared by Janssen Pharmaceutica, Inc. 20 p. {OPPTS 875.2700, 875.2800}

46177100 Janssen Pharmaceutica (2004) Submission of Product Chemistry Data in Support of the Application for Registration of XAMOX 3OL. Transmittal of 1 Study.

46429400 Janssen Pharmaceutica (2004) Submission of Product Chemistry Data in Support of the Application for Registration of Xamox 3OL. Transmittal of 1 Study.

46429401 Helmer, D. (2004) Supplemental to MRID 4578913: 36 mo. Evaluation; Interim Report: Field Termite Test of Commercial Wood Composites Treated with Janssen Experimental Termiticides. Project Number: E26639. Unpublished study prepared by Michigan Technological University. 9 p.

46494200 Janssen Pharmaceutica Inc. (2005) Submission of Exposure and Risk Data in Support of the Application for Registrations of Xamox 3OL and Xamox 100 SL. Transmittal of 2 Studies.

46554600 Janssen Pharmaceutica, Inc. (2005) Submission of Environmental Fate, Exposure and Risk Data in Support of the Application for Registration of Xamox 3OL and Xamox 100 SL. Transmittal of 2 Studies.

46554601 Bylemans, D. (2005) Surface Wipe Test of R170051 from Wood Blocks Treated with Xamox 3 OL and Xamox 100 SL. Project Number: 05038, 059/2005, AGR/1139. Unpublished study prepared by Janssen Pharmaceutica. 129 p.

46554602 Bylemans, D. (2005) Leaching of R170051 After Artificial Rainfall on Scots Pine Sapwood (*Pinus sylvestris*) Treated with Xamox 100SL and 3 OL. Project Number: 05029, 60/2005, AGR/1128. Unpublished study prepared by Janssen Pharmaceutica. 65 p.

46567600 Janssen Pharmaceutica, Inc. (2005) Submission of Product Chemistry Data in Support of the Application for Registration of Xamox 3OL. Transmittal of 1 Study.

46632600 Janssen Pharmaceutica Inc. (2005) Submission of Efficacy Data in Support of the Application for Registrations of Xamox 3OL and Xamox 100 SL. Transmittal of 1 Study.

47651500 Janssen PMP (2009) Submission of Efficacy Data in Support of the Amended Registration of Xamox 100 SL. Transmittal of 2 Studies.

47651501 Nicholas, D.; Schultz, T. (2008) Evaluation of a New Insecticide Against Formosan Termites: (Xamox 100 SL): Final Report. Project Number: JNDDN/8. Unpublished study prepared by Mississippi State University: Forest and Wildlife Research Center. 17 p.

47651502 Larkin, G.; Keranen, E.; Laks, P. (2008) Field Termite Test of Commercial Wood Composites Treated with Janssen Experimental Termiticides - May 2006 Protocol: 30-Month Interim Report: (Xamox 100 SL). Project Number: E26641B/20081211. Unpublished study prepared by Michigan Technological University: School of Forest Resources and Environmental Science. 43 p.

48166100 Janssen PMP (2010) Submission of Efficacy and Product Chemistry Data in Support of the Amended Registration of Xamox 100 SL. Transmittal of 4 Studies.

48166101 Nicholas, D.; Schultz, T. (2010) Evaluation of a New Insecticide Against Formosan Termites (Xamox 100SL). Project Number: JNDDN/8. Unpublished study prepared by Mississippi State University. 35 p.

48166102 Nicholas, D.; Schultz, T. (2010) Evaluation of a New Insecticide against *Reticulitermes* Termites (Xamox SL 100): Final Report. Project Number: JNDDN/10. Unpublished study prepared by Mississippi State University. 35 p.

48166103 Larkin, G.; Laks, P. (2010) Field Termite Test of Commercial Wood Composites Treated with Janssen Experimental Termiticides (Xamox 100 SL) - May 2006 Protocol: 48 Month Interim Report. Project

Number: E26641B/20100723. Unpublished study prepared by Michigan Technological University. 82 p.